REMARKS

Upon entry of the present amendment, the claims in the application the claims in the application remain claims 1, 3-11 and 13-21, of which claims 1 and 4 are independent.

All claims have been rejected by the Examiner under 35 USC 103(a) based on combinations of references. Applicant has carefully considered each of the rejections set forth in the Office Action, but applicant respectfully traverses each of the rejections because it is applicant's position that the Examiner has not established prima facie obviousness of any of the present claims under 35 USC 103(a) as discussed herein.

Art-Based Rejections

1. In item 1 of the Office Action, the Examiner has rejected claims 1, 3-7 and 9-13 under 35 102(b) (? It appears that the rejection is actually under USC 103(a)) as unpatentable over Soller et al. (U.S. patent 6,006119) in view of Benz et al. (US Patent 5,982,501). It is essentially the Examiner's position that: Soller teaches most aspects of the claimed invention; it would have been obvious to persons skilled in the art at the time of the invention to hypothetically modify Soller's apparatus to include use of a ceramic plate as a reference material to obtain a reference value for measurements of an optical sensor based on select teachings of Benz; and it would have been obvious to persons skilled in the art at the time of the invention to hypothetically modify Soller's apparatus to include other aspects of the claimed invention as general matters of conventional knowledge or practice.

Applicant's Response

Upon careful consideration applicant respectfully traverses such rejection, and submits that each of present claims 1, 3-7 and 9-13 is clearly patentably distinct over the Soller and Benz references, for those reasons as argued in the Amendment Under 37 CFR 1.116 dated 23 October 2003, for the reason that the proposed modification of Soller's apparatus relative to a select feature of the Benz reference is improperly based on a suggestion coming entirely from the Examiner (as guided by impermissible hindsight of applicant's disclosure), rather than from any

teaching or suggestion which may be drawn from the references themselves, and for the reason that Benz does not disclose or suggest a ceramic plate as claimed.

Regarding the Soller reference, applicant respectfully submits that Soller's disclosed method is significantly and fundamentally distinct from the presently claimed invention not only because he fails to use measured intensity of light transmitted through a ceramic plate as a reference value, but also because he fails to teach or suggest several other important aspects of the claimed invention, including use of an ordinary (off the shelf) test tube or bag as a receptacle for *both collecting and analyzing* a blood sample, wherein the analysis is performed using near infrared light with a wavelength in a range of 700nm – 1100nm, and use of a calibration equation *generated using an ordinary test tube or bag with the same specifications as the ordinary test tube or bag* used for blood collection and analysis.

Rather, Soller's disclosed method involving use of special quartz cuvette 1061for collecting and analyzing a liquid sample is nothing more than the disadvantageous methods disclosed in the background of the present application which also involve use of a special liquid sample cell e.g., Soller expressly states that "A [the same] cuvette holder 1060 and a quartz cuvette 1061 was used through the entire experiment (emphasis added)". Correspondingly, Soller does not achieve or in any way suggest the very great advantages of the present invention, e.g., the practical ability to use an ordinary test tube or bag for field measurements, such that if the tube or bag is accidentally broken, another ordinary tube or bag can be used in its place without having to recalibrate the system.

Additionally, applicant notes that according to Soller's method the quartz cuvette 1061 used in measuring blood samples is *not the same as* the receptacle used to a collect 500 ml sample from a pig , as discussed at Soller's col. 19, line 45 – col. 20, line 42, nor is it the same type of receptacle as Soller uses to generate his calibration equation because Soller specifically uses capillary tubes (not the quartz cuvette 1061) for generating his calibration equation, as discussed at his col. 20, lines 1-5.

Still further, the discussion of Figs. 14A-15 at Soller's col. 19, line 32 – col. 20, line 42 indicates that in vitro measurements of collected blood samples using the apparatus of Fig. 14A involves processing the collected blood samples before analyzing same similar to the

disadvantageous methods mentioned at page 1, lines 16-27 of the present specification.

With regard to the proposed modification to Soller's method based on Benz, applicant respectfully submits that the devices/methods disclosed in these two references are so distinct that persons of ordinary skill in the art would not consider the Examiner's proposed hypothetical modification of Soller's method to have been obvious at the time of the present invention because the references provide no motivation for the modification. On the one hand, Benz' reflectance measuring device relates to analysis of (solid) objects, rather than to analysis of liquid (blood) samples contained in a special quartz cuvette such as in the method of Soller which the Examiner is applying in the rejection. On the other hand, Soller already specifically provides that a reference value for his analysis method is acquired "... using the blank cuvette as a reference" (see his col. 20, lines 14-17). Thus, the specific reason why Benz uses black, gray and white calibration tiles in checking the linearity of his measuring system does not exist in Soller's in vitro blood sample measurements, and as such there is no reason which can be fairly gleaned from the references for making the modification.

Appellant notes that the Courts and the Board of Patent Appeals and Interferences (BPAI) have consistently held that, for purposes of establishing obviousness under 35 USC §103, a rejection advanced by an Examiner must rest on a factual basis, with the facts being interpreted without hindsight reconstruction of the invention from the prior art, and that the Examiner may not, because of doubts that the invention is patentable, resort to speculation, unfounded assumption or hindsight reconstruction to supply deficiencies in the factual basis. Ex Parte Hamond, 41 USPQ2d 1217, 1220, citing In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968). It is respectfully submitted that the Examiner's rejection, particularly the proposed modification to Soller's in vitro measurement method, is based on such impermissible hindsight reconstruction, speculation, etc. which the courts warn against.

Still further, applicant respectfully submits that the black, gray and white calibration tiles used by Benz are not a ceramic plate as defined in the present claims, such that any hypothetical

combination of the actual teachings of the Soller and Benz references would not, in any event, achieve or make obvious the claimed method involving use of a ceramic plate *through which light is transmitted* for calibration purposes. Benz only teaches about a "gray stage wedge" (at his col. 4, line 52) that uses one black tile, two gray tiles and one white tile. Since Benz only teaches a *reflectance device*, the measuring light is reflected off the calibration tiles. No measuring light is transmitted through the tiles.

Applicant notes the examiner's allegation that it would have been obvious ... to combine the white tile of Benz with Soller's in vitro measuring method to achieve the presently claimed invention. However, applicant respectfully submits that the function of the white tile in Benz is for *reflection* of light, and hence completely teaches away from the presently claimed invention in which light is transmitted *through the ceramic plate*. See also the discussion of the ceramic plate and its function at page 5 of the present specification.

Based on the foregoing, applicant respectfully submits that the Examiner has not established prima facie obviousness of the subject matter of any of and of claims 1, 3-7 and 9-13 under 35 USC 103(a). Accordingly, it is respectfully requested that the rejection based on the Soller and Benz references be reconsidered and withdrawn.

2. In items 2-4 of the Office Action, the Examiner has also rejected: claim 8 under 35 USC 103(a) as being unpatentable over Soller in view of Benz and further in view of Brown et al. (US 4,134,678, hereinafter Brown); claims 14-16, 19 and 20 under 35 USC 103(a) as being unpatentable over Soller in view of Benz and further in view of Kuenstner (US 6,285,448); and claims 17 and 21 under 35 USC 103(a) as being unpatentable over Soller in view of Benz and further in view of Ikeda et al. (US 4,936,674, hereinafter Ikeda).

It is the Examiner's position that while Soller does not teach a temperature control means as defined in claim 8, analysis of multiple different components of blood, or an optical path length for a blood sample receptacle of 1-2cm: it would have been obvious at the time of the invention to provide Soller's method and apparatus with such a temperature control means based

on the teachings of Brown; to analyze multiple different components of blood based on the teachings of Kuenstner, and to provide an optical path length for the blood sample receptacle of 1-2cm based on the teachings of Ikeda.

Applicant's Response

Upon careful consideration applicant respectfully traverses such rejection, and submits that each of present claims 8, 14-17 and 19-21 is clearly patentably distinct over the applied references, for substantially those same reasons discussed above in relation to the deficiencies of Soller and Benz (which are not overcome by the teachings of the additional references), and (again) because the proposed modification of Soller's apparatus relative to a select teaching of the Ikeda reference, as proposed by the Examiner is improperly based on a suggestion coming entirely from the Examiner, rather than from any teaching or suggestion which may be fairly gleaned from the references themselves, as argued at page 12 of the Amendment Under 37 CFR 1.116 dated 23 October 2003., i.e., persons skilled in the art would not consider it obvious to combine/modify Soller's apparatus with Ikeda's sample containment chamber because the references do not provide any motivation for doing so in that the respective apparatus are structured different to achieve different purposes, while Ikeda's discussed optical path length is distinct from and does not make obvious the claimed feature, i.e., Ikeda's path length pertains to the cell suspension, not to the blood sample (collection) receptacle as claimed.

Based on the foregoing, applicant respectfully submits that the Examiner has not established prima facie obviousness of the subject matter of any of and of claims 8, 14-17 and 19-21 under 35 USC 103(a). Accordingly, it is respectfully requested that the rejections based on the Soller, Benz, Brown, Kuenstner and Ikeda references be reconsidered and withdrawn.

Conclusion

In conclusion, applicant has overcome the Examiner's rejections as presented in the Office Action; and moreover, applicant has considered all of the references of record, and it is respectfully submitted that the invention as defined by each of the present claims is clearly patentably distinct

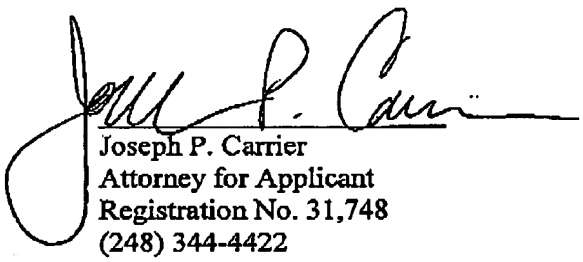
thereover.

The application is now believed to be in condition for allowance, and a notice to this effect is earnestly solicited.

If the Examiner is not fully convinced of all of the claims now in the application, applicant respectfully requests that the Examiner telephonically contact applicant's undersigned representative to expeditiously resolve prosecution of the application.

Favorable reconsideration is respectfully requested.

Respectfully submitted,



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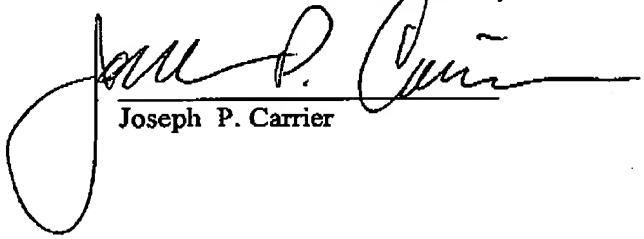

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